

Miracle-Ear®

September 27, 2000

8176 '00 OCT 19 P2:03

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W. Room 615F
Washington, D.C. 20201

Dear Secretary Shalala:

I am a small business owner in Northern Utah, providing hearing health care services to the areas's hearing impaired. I am very concerned that the Food and Drug Administration (FDA) is reportedly advocating changes to the current hearing aid regulations that would dramatically increase the cost of hearing health care and reduce access to hearing health care providers. Please take the time to consider the impact of this proposed hearing aid rule on the nation's hearing-impaired and on the nation's small business hearing health care providers, as required by the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Hearing health care providers like me have been working with the FDA since 1993 to streamline the current FDA hearing aid regulations. Now just weeks before the election of a new Administration, FDA is rushing to put forth a proposal that could eliminate hearing aid specialists like me from the marketplace. FDA reportedly favors allowing each state to determine the conditions for dispensing hearing aids. This will create inconsistency and confusion and will launch a 50-state effort by audiologists to install themselves as the sole gatekeepers to hearing health care without any medical or health policy justification.

As you may have seen, the AARP recently published a *Consumer Guide to Hearing Aids* which found that "almost everyone with a hearing loss hears better with a hearing aid, yet only 20 percent of those who need a hearing aid have one." Please don't let the FDA erect unwarranted barriers to this safe and effective medical device.

Please don't let the FDA publish its proposed hearing aid rule.

Sincerely,

Blake J. Webb, BC-HIS
Owner, Miracle-Ear

93M 0372

3330 South 700 East
Salt Lake City, UT 84106
(801) 483-2282

Sears Fashion Place
6191 South State St.
Murray, Utah 84107
(801) 266-3751

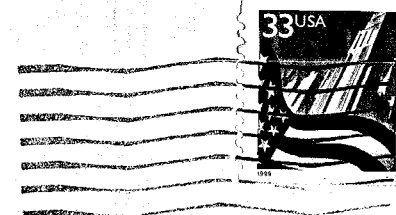
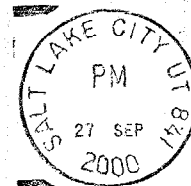
C 4707
1000 Newgate Mall
Ogden, Utah 84405
(801) 392-0992



Miracle-Ear®

3330 South 700 East
Salt Lake City, UT 84106
(801) 483-2282

An independently owned and operated franchise.



Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Ave, S.W.
Room 615F
Washington, D.C. 20201

